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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,521	05/01/2002	Dan L. Eaton	P3230R1C001-168	8152

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EXAMINER	
SPECTOR, LORRAINE	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,521	EATON ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/10/2002.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Part III: Detailed Office Action

Claims 1-6 are pending and under consideration.

The claims are drawn to antibodies that bind the protein designated PRO1063, also identified as encoded by DNA49820-1427 and ATCC accession number 209932, shown in Figures 17 (nucleic acid) and 18 (protein).

Formal Matters and claim objections:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

This application lacks a paper copy of the sequence listing, as required by 37 C.F.R. §1. 821(c). Applicants are required to submit such in response to this office action, and are further reminded that a statement in compliance with 37 C.F.R. §1. 821(f) must be made at such time.

Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. An antibody cannot be a fragment of itself.

IDS:

The information disclosure statement, filed 9/10/2002, has been considered. The BLAST results demonstrate that applicants are aware of nucleic acids with identity/homology to the one claimed herein. However, as the BLAST results do not give sufficient identifying information, the Examiner cannot determine if said sequences constitute prior art. Also, since database searches are not publications, they will not be printed on the face of the patent.

Priority Determination:

This invention is found to lack utility, see rejections below. Accordingly, priority is merited only to the filing date of Application Serial Number PCT/US00/23328, filed 8/24/2000, of which this is a continuation application.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to the date recited above which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to that date.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

The specification discloses a protein designated PRO1063, and nucleic acid encoding such. There is no discussion of the structure of the protein encoded by the claimed nucleic acids, nor disclosure of any relationship between such structure and a purported function. There is no disclosure of any disease or condition in any way related to the claimed protein, nor disclosure of any diagnostic or analytical assay that could be performed using the claimed protein or antibodies thereto.

The claims are directed to antibodies that bind to the polypeptide of SEQ ID NO:18. The specification contains numerous asserted utilities including use in immunoassays (p. 95), use in chemotherapeutics (p. 109), and pharmaceutical compositions (pp. 109-110). Use in

diagnostic assays or for immunopurification of PRO1063 protein are disclosed at page 113. None of these asserted utilities is specific for the disclosed PRO1063 antibodies, as each of the aforementioned utilities could be asserted for any antibody that binds naturally occurring protein, and further, as none of the asserted utilities requires any feature or activity that is specific to the disclosed PRO1063.

Utility must be in readily available form. In Brenner v. Manson, 148 U.S.P.Q. 689 (Sup. Ct,.1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a polynucleotide encoding a protein which has undetermined function or biological significance. Until some actual and specific activity can be attributed to the protein identified in the specification as PRO295 protein or the polynucleotides encoding it, the claimed invention is incomplete. Merely using the polynucleotides to determine the properties of the encoded protein does not constitute a patentable utility.

Uses of anti-PRO1063 antibodies in diagnostic compositions, or chemotherapeutic or other pharmaceutical compositions are not considered to be substantial assertions in the absence of any condition or disease that could be diagnosed using such, nor any medical condition for which the PRO1063 protein would be a target for therapeutic administration. There is no disclosure of the expression patterns of the protein that would allow such use, nor, in fact, is it even disclosed whether the protein is soluble or membrane bound, as would be require for such use. Similarly, immunoassay of PRO1063 is mere further experimentation to determine the properties of the protein, and not a patentable utility. Hence, the specification is merely an invitation to experiment to find uses for the claimed antibodies.

It is further noted that PRO1063 is disclosed as having given positive results in a single assay, the stimulation of TNF-α release in human blood, assay 128, at page 139. In that assay, it

is stated that the PRO polypeptide was added to human blood, and then tested for the presence of TNFα by ELISA assay. It is stated that "A positive in the assay is a higher amount of TNF-α in the PRO polypeptide treated samples as compared to the negative control samples." This assay is not considered to impart utility to the protein PRO1063, and by extension, to the antibodies that bind it. The reason for this determination is that no results are presented, and the standard disclosed, "a higher amount", is not considered to be an acceptable standard in the scientific community. It is well accepted in experimental science that, in order for a result to be positive, it must be *significantly* different from the control value, not "a higher amount" as reported in the specification. In this case, it is further noted that the protein (TNF-α) was detected using an extremely sensitive immunoassay, such that "a higher amount" does not indicate anything more than that a trace amount of TNF-α was present. Therefore, the assertion that the protein could be used "where stimulation of the release of TNF-α would be desired and for the therapeutic treatment of conditions wherein enhanced TNF-α release would be beneficial" is not substantial. The Examiner further notes that she is unaware of *any* condition in which stimulation of TNF-α release in the bloodstream would be desirable, even if, *in arguendo*, significant amounts of the cytokine were produced. Accordingly, the tacit assertion that PRO1063 stimulates TNF-α release from blood cells does not meet the requirements of 35 U.S.C. § 101, as the assertion of utility would not be considered substantial by a person of ordinary skill in the art.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 states that the claimed antibody "binds" the protein of SEQ ID NO: 18, whereas dependent claim 6 states that the antibody "specifically binds". The term "specifically" in claim 6 is a relative term which renders the claim indefinite. The term "specifically" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Further, because both "binds" and "specifically binds" have been used in the claims, the Examiner cannot determine whether claims 1 and 6 are envisioned as differing in scope, and if so, how.

Claim 4 is indefinite because an antibody cannot be a fragment of itself.

The remaining claims are rejected for depending from an indefinite claim.

Rejections Over Prior Art:

Priority is set at 8/24/2000.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Lal et al., U.S. Patent No. 5,932,445.

Lal's SEQ ID NO: 11 is 96.5% identical to SEQ ID NO: 17 of the instant application at residues 1-960. See claim 1 of Lal, and attached alignment. As the first "ATG" of SEQ ID NO: 17 occurs beginning at residue 61, and the encoded protein is 301 amino acids, the nucleic acid of Lal encodes the protein of SEQ ID NO: 18 with 100% identity. At column 7, antibodies are defined as ingcluding antibody fragments. Monoclonal and polyclonal antibodies are disclosed at the paragraph bridging columns 20-21. Further discussion of antibodies, including monoclonal, polyclonal and humanized antibodies, is found at column 24. Accordingly, the invention as claimed is anticipated by Lal et al.

Advisory Information:

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to 571-273-8300. Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector

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Primary Examiner